US PUBLIC HEALTH SERVICE REGULATIONS FOR
FINANCIAL CONFLICTS OF INTEREST

Training for Responsible Conduct in Research Seminar Series
October 4, 2012
New Financial Conflicts of Interest Regulations became effective August 24, 2012.

- Applies to **ALL** research funded by the Public Health Service (PHS), which includes the National Institutes of Health (NIH) and all sub-agencies.
What lead to the changes in the regulation?

Senator Chuck Grassley, (Rep., Iowa) spearheaded the investigation of academic researchers receiving remuneration from drug companies.
Emory University

- Beginning in 2008, the US Senate Finance Committee – spearheaded by Sen. Grassley – investigated the financial relationships between academic researchers who are federal grant recipients and pharmaceutical companies.

- Sen. Grassley’s investigation found a timeline of payments received by Dr. Charles Nemeroff during a timeframe when he assured Emory COI administrators he would receive no more than $10,000 annually in consulting fees from GlaxoSmithKline.
Emory COI Case

- At the time, Dr. Nemeroff was the PI on an NIH grant between Emory and GlaxoSmithKline (GSK).
- The grant, with a budget of $3.95 million, examined five emerging GSK antidepressant drugs.
- During the life of the grant it was found that Dr. Nemeroff failed to disclose to Emory that he received over $500K from GSK for consulting, speaker’s fees, conferences he attended to promote some of the drugs being studied. He also published journal articles praising treatments for depression in which he had an unreported financial interest.
- Why is this a conflict of interest?
Emory COI Case

- Correspondence and emails between Emory administrators and Nemeroff were widely published in the media (NY Times, WSJ, etc.) causing embarrassment for the university.
- The grant was frozen by NIH in 2008 due to the Grassley findings.
- In addition, Emory elected to not submit proposals, for a two year period, to NIH with Dr. Nemeroff participating as an investigator. Emory also imposed strict monitoring of all of Dr. Nemeroff’s outside activities.
Emory COI Case

- Dr. Nemeroff was asked to step down as Chair of Psychiatry in 2008. However, Dr. Nemeroff then moved to Univ. of Miami in 2009 as Chair and Professor!
- In 2010, it was reported that the head of the National Institutes of Mental Health (NIMH), a sub-agency of NIH had recommended Nemeroff to the U. of Miami and was encouraging him to apply for more NIH grants!
Harvard COI Case

- In July 2011 it was reported that, after a three-year investigation, Massachusetts General Hospital and Harvard Medical School sanctioned renowned child psychiatrist Dr. Joseph Biederman and two colleagues after finding they violated conflict of interest rules.
- Sen. Grassley accused Drs. Biederman, Spencer, and Wilens of failing to disclose to Harvard more than $1 million each in payments they received from industry over a period of eight years.
- Biederman was the country’s most prominent advocate of diagnosing bipolar disorder in children, even in those under age 6, and using antipsychotic drugs to treat many of them.
Harvard COI Case

- The institutions imposed remedial actions, requiring the three faculty to refrain from all paid industry-sponsored outside activities for one year, with an additional two-year monitoring period during which they must obtain approval before engaging in paid activities.

- They were also required to undergo unspecified additional training and suffer “a delay of consideration for promotion or advancement.”
Changes to PHS Regulations regarding Financial Conflicts of Interests (FCOI) by Researchers and Key Personnel

- Final Rule was issued on 8/25/2011
- Institutions have until 8/24/2012 to update their Conflict of Interest policies to be compliant with the new regs.
- Since Tulane is a recipient of PHS funding, Tulane enacted new FCOI policies that became effective on August 24, 2012.
Conflict of Interest (COI) as it relates to NIH funded research

A COI is a situation when an Investigator or key personnel on the project has a relationship or obligation with another entity that has the potential to undermine his/her objectivity and independent judgment when designing/performing research, sharing results, etc.

PHS regs. state: a financial conflict of interest exists when the grantee's designated official(s) reasonably determines that an investigator's or key personnel’s significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
Why is this important to PHS?

The purpose is to protect patients and humans subjects and to preserve research objectivity and scientific integrity from being corrupted by personal gain.

Reflect on the example of Dr. Nemeroff.
Who must disclose?

“Investigators”, which includes the principal investigator, key personnel, and “other significant contributors” identified in the proposal, progress report, or any other report submitted to PHS. The rule applies to all individuals, regardless of title or position, who are responsible for the design, conduct, or reporting of research funded by the PHS. This may include collaborators or consultants.

- Postdocs, graduate students, coordinators, technicians, etc., may not always be considered significant contributors.
- The inclusion of a Biosketch in an application is a signal that an individual may be a significant contributor in the design, conduct, and reporting of PHS funded research.
What must be disclosed?

- A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children). A significant financial interest (SFI) is triggered when remuneration exceeds $5,000 for the 12 months preceding the disclosure.

- Remuneration includes
  - salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship)
  - equity interest includes any stock, stock option, or other ownership interest
  - income from patents and copyrights owned by the outside entity

- Travel: any reimbursed or sponsored travel paid for by certain entities (more on this on the following slides)
Financial Interests requiring disclosure (continued)

PHS Investigators are required to disclose reimbursed or sponsored travel, *of any value*, related to the individual’s responsibilities to Tulane for teaching, research, patient care and welfare, and service.

- There is no dollar threshold for travel.
- Travel paid on behalf of Investigator must be disclosed even if the exact value may not be readily available.
Financial Interests requiring disclosure (continuation)

• Travel paid or sponsored by non-profit organizations (e.g. American Cancer Society, Gordon Conference, Pfizer Foundation, Foreign universities, ministries, etc.) must be disclosed.

• However, investigators do not have to disclose travel that is reimbursed or sponsored by Tulane, government agencies, other institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with an institution of higher education.
What types of Financial Interests are excluded from disclosure?

- Income from investments such as mutual funds and retirement accounts, as long as the PHS Investigator does not directly control the investment decisions;
- Salary, royalties, or other pay from Tulane to PHS Investigators employed by Tulane;
- Royalties paid to Tulane employees from intellectual property rights assigned to Tulane;
What types of Financial Interests are excluded from disclosure? (continued)

- Income from seminars and lectures sponsored by government agencies, other institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with an institution of higher education.
- Travel that is reimbursed or sponsored by Tulane, government agencies, other institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with an institution of higher education.
What types of Financial Interests are excluded from disclosure? (continued)

• Income from advisory committees or review panels for government agencies, other institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with an institution of higher education.
When should COI info be disclosed?

(1) no later than at the time of application for NIH-funded research; this is collected and certified on the Proposal Routing Form

(2) within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest (remember, a SFI is triggered when remuneration exceeds $10,000 for the 12 months preceding the disclosure); and

(3) at least annually, in accordance with the specific time period prescribed by the Institution, during the period of award. This is done annually at Tulane by January 31st of each year. Reminders to submit annual disclosures are sent by Tulane via email.

All disclosures are done via Tulane’s online COI disclosure system: http://coi.tulane.edu/
Proposal submissions

PI must sign the assurance and COI disclosure with each proposal submission routing form.

The PI’s signature on the routing form provides attestation that all key personnel involved in the proposed project have complied with Tulane’s policy on COI disclosures - annually and updating as needed.
Disclosure review by the Tulane COI Committee

The COI Committee will review the disclosures of Tulane’s PHS Investigators and Affiliated PHS Investigators to determine whether any interest is:

- related to PHS-Funded Research; and
- a PHS Financial Conflict of Interest.
Disclosure review by the COI Committee (continued)

- If the COI Committee determines that an actual Conflict of Interest exists, it will work with Faculty or Staff or Affiliated PHS Investigators to manage, reduce or eliminate the Conflict.

- The COI Committee may require that the Faculty Staff or Affiliated PHS Investigator comply with a particular management plan for managing a conflict. The management plan must be implemented before the expenditure of any funds under a PHS-Funded project - for example, returning monies received over the $10,000 threshold; getting someone else to interpret the data; having someone consent potential participants; etc.
Reporting FCOIs to PHS

Sponsored Projects Administration (SPA) must report to NIH any identified FCOIs for Tulane PHS Investigators, Affiliated PHS Investigators and Subrecipient PHS Investigators.

PHS regulation establishes the timing/frequency and contents of such reports.
Management of Identified FCOIs

The PHS regulation permits the Institution to determine how to manage an identified FCOI. PHS suggests the following examples of conditions or restrictions that might be imposed to manage an FCOI:

- Public disclosure of FCOIs (e.g., when presenting or publishing the research);
- For projects involving human subjects research, disclosure of FCOIs directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
Management of Identified FCOIs (continued)

- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts
Management of Identified FCOIs (continued)

- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts
Retrospective reviews and Mitigation Reports

A retrospective review (by the Tulane COI committee) and mitigation report is triggered when an FCOI has not been identified or managed in a timely matter. For example:

- When an Investigator does not disclose any interest that Tulane later determines to be an FCOI
- If Tulane fails to review or manage such an FCOI;
- If the Investigator does not comply with a management plan
Retrospective reviews and Mitigation Reports (continued)

In those events, within 120 days, Tulane must complete a retrospective review of the circumstances to determine if any research activities conducted during the time of non-compliance, was biased in the design, conduct or reporting of such research.

• If bias is found, Tulane must notify NIH promptly and submit a mitigation report to the NIH
Retrospective reviews and Mitigation Reports (Continued)

The mitigation report must include, at a minimum:

- A description of the impact of the bias on the research project
- The plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).
- Thereafter, FCOI reports must be submitted annually as prescribed by the PHS regulation.
Public Access to Tulane’s COI Policy and Identified FCOIs

To comply with the PHS regulation, Tulane’s Policies on Conflicts of Commitment and Interest must be posted on a publicly accessible website.

In addition, if any Tulane Investigator, Affiliated PHS Investigator or PHS Subrecipient Investigator has an FCOI, the University is required to make publically available certain information about the interest prior to the expenditure of any funds for the PHS-Funded Research.
Public Access to Tulane’s COI Policy and Identified FCOIs

The University must make the following information publicly available by providing in writing within five days in response to a request:

- the name, title and role of the individual with the Financial Interest;
- the entity with which the Financial Interest is held; and
- the nature and approximate value of the Financial Interest.
What to expect as a PHS Investigator

- At the time of proposal submission for PHS funds, Sponsored Projects Administration ("SPA") will confirm with General Counsel’s Office that the PI and all key personnel listed in your proposal have provided annual disclosures. This applies to all award types (e.g. New, Continuation, Renewal, Revision). Early notification to SPA about your proposal submission will facilitate this verification process.
What to expect as a PHS Investigator

- Investigators must complete required COI training prior to the issue date of the Notice of Award from PHS. Therefore, no award money may be spent or research begun prior to completion of COI training.

- Training is conducted online via the CITI training program - [www.citiprogram.org](http://www.citiprogram.org).

- If you serve as an Investigator (e.g. consultant or “other significant contributor”) on another institution’s proposal, you may be required to follow that institution’s requirements for training and making disclosures.
Links to more information

- NIH: Public Policy Requirements and Objectives—Financial Conflict of Interest
- NIH Frequently Asked Questions about new regulations
- NIH Tutorial on FCOI regulations
- Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought, 42 CFR 50
- Tulane University COI Policy
- Senator Grassley’s Drug Payments to Doctors COI website
Select COI Cases Listed on Senator Grassley’s Website

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